APR 1 5 2002

K020134

510(k) SUMMARY

Surgical Dynamics™, 150 Glover Avenue, Norwalk, CT 06856 USA

CONTACT PERSON: Jenny Schuck
PRODUCT NAME: Spiral Radius 90-D Rodding System
CLASSIFICATION NAME: Spinal Intervertebral Body Fixation Orthosis
Spinal Interlaminal Fixation Orthosis
Spondylolisthesis Spinal Fixation Device System
PREDICATE DEVICE: Surgical Dynamics Rodding System

DEVICE DESCRIPTION

The Spiral Radius 90-D Rodding System consists mainly of 1) screws and hooks that are implanted in vertebral bodies and 2) rods that fit into and are locked upon the screw heads using a locking cap. The system also includes crossbars that connect 2 parallel-running rods, offset screws and clips that allow a rod to be placed in certain situations where a direct connection to the vertebrae would cause excessive bending of the rod, and rod-to-rod connectors that allow a construct to be extended. All components of the system are composed of Ti-6Al-4V which conforms to ASTM F136.

INDICATIONS FOR USE

When used as an anterolateral/anterior system, the levels of attachment are the lumbar, thoracic, and cervical spine. The points of attachment are screw fixation into the anterolateral vertebral bodies of the lumbar and thoracic spine (T1-L5) and anterior vertebral bodies of the cervical spine. The indications are degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, fracture, spinal stenosis, deformities (i.e., scoliosis, kyphosis, lordosis), tumor, pseudoarthrosis, or failed previous fusion.

When used as a nonpedicle, posterior system consisting of hooks, crosslinks, and sacral/iliac screws, the levels of attachment are the lumbar, thoracic, and cervical spine and the sacrum and ilium. The indications are degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, fracture, spinal stenosis, deformities (i.e., scoliosis, kyphosis, lordosis), tumor, pseudoarthrosis, or failed previous fusion.

When used as a pedicle screw system in the non-cervical spine of skeletally mature patient, the system is indicated for patients: (a) having severe spondylolisthesis (Grades 3 and 4) at L5-S1 joint; (b) who are receiving fusions using autogenous bone graft only; (c) who are having the device fixed or attached to the lumbar and sacral spine (L3 and below); and (d) who are having the device removed after the development of solid fusion mass.

In addition, when used as a pedicle screw system in the non-cervical spine of skeletally mature patients, the system is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis).

The Surgical Dynamics Spiral Radius 90-D Rodding System is to be used in conjunction with the SDRS Spinal Rods, SDRS Spinal Rod with Sacral Eye and the SDRS Locking Screw.

TESTING
Mechanical testing was performed, including static and dynamic compression testing and static torsion testing.

SUBSTANTIAL EQUIVALENCE*
The components added to the Spiral Radius 90-D Rodding System were claimed to be substantially equivalent* to components of the Surgical Dynamics Rodding System (K970635). The Spiral Radius 90-D Rodding System Rod-to-Rod Connector was claimed to be substantially equivalent* to the Spinal Concepts BacFix End-to-End Connector and the Spiral Radius 90-D Rodding System Multi-Angle Screw/Rod construct. Information pertaining to these devices was provided in the submission.

*Any claim of substantial equivalence is made exclusively in regard to the U.S. Food, Drug and Cosmetic Act and should not be viewed in any other light.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 5 2002

Ms. Jenny Schuck
Regulatory Affairs Senior Associate
United States Surgical
150 Glover Avenue
Norwalk, Connecticut 06856

Re: K020134
Spiral Radius 90-D Rodding System
Regulation Numbers: 888.3050; 888.3060; and 888.3070
Regulation Names: Spinal Interlaminal Fixation Orthosis; Spinal Intervertebral Body Fixation Orthosis; Spondylolisthesis Spinal Fixation Device System; and Pedicle Screw Spinal System
Regulatory Class: II
Product Codes: KWP, KWQ, MNI, MNH
Dated: January 14, 2002
Received: January 15, 2002

Dear Ms. Schuck:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

for Mark N Milhern

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative,
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS ENCLOSURE

510(k) Number (if known): K020134

Device Name: Spiral Radius 90-D Rodding System

Indications For Use:

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(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: X OR Over-The-Counter Use: _____
(Per 21 CFR 801.109)

Mark N Melkerson
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K020134